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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/706,300 | 11/12/2003 | Hosheng Tu | GLAUKO.1C3CP1 | 5751 |
| 20995 7590 08/24/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | EXAMINER DEAK, LESLIE R | |
| | | | ART UNIT 3761 | PAPER NUMBER |
| | | | NOTIFICATION DATE 08/24/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/706,300 | TU ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 June 2007 has been entered.

Information Disclosure Statement

2. The references cited by applicants in the information disclosure statement filed 23 February 2007 have been made of record. Examiner has considered the voluminous references to the best of her ability.

While the statements filed do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references. However, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure. See Penn Yan Boats, Inc. v. Sea Lark boats Inc., 359 F. Supp. 948, *aff'd* 479 F. 2d. 1338.

Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability. MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), states that forcing the Examiner to find “a needle in a haystack” is “probative of bad faith.” *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

The MPEP provides more support for this position. In a subsection entitled “Aids to Compliance With Duty of Disclosure,” item thirteen states:

*It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974). See also MPEP § 2004.*

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statement is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 5, 46, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,450,984 to Lynch et al.

In the specification and figures, Lynch discloses the apparatus as claimed by applicant. With regard to claims 1, 2, 4, 5, 46, and 47, Lynch discloses an implant 100 with a body comprised of a biocompatible material that may comprise a drug or therapeutic agent deliverable to adjacent tissues (which indicates the agent is located on the outside of the implant, meeting applicant's limitation drawn to a coating) wherein the implant comprises an outlet end or distal portion sized and shaped to reside in a physiological outflow pathway such as Schlemm's canal, and an inlet end or proximal portion sized and shaped to reside in the anterior chamber of the eye, wherein the device permits fluid communication from the anterior chamber to Schlemm's canal (see column 6, lines 50-64, column 9, lines 49-67).

With regard to claim 15, Lynch discloses that the device may be made of various polymers (see column 9, lines 60-67).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al.

In the specification and figures, Lynch discloses a method of introducing an implant into the claimed location to facilitate drainage, and may incorporate advancing a therapeutic drug (see rejection above). In the provisional application, Lynch fails to specifically disclose the particular drainage method in conjunction with therapeutic drug delivery, but does disclose the drainage and drug delivery as separate procedures. Accordingly, the Lynch disclosure reasonably suggests the method claimed by applicant, rendering the instantly claimed method unpatentable over the prior art.

7. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 7,033,603 to Nelson.

In the specification and figures, Lynch discloses the device substantially as claimed by applicant (see rejection above) with the exception of the particular drugs or materials used as bioactive agents in the device. Nelson discloses an implantable hydrogel device that provides drug delivery to various internal locations within a patient. The device disclosed by Nelson may include a growth factor, a gene, TGF-beta, and heparin (see column 7, lines 60-67, column 8, lines 1-22, column 18, lines 50-67,

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column 17, lines 36-41). It has been held to be within the general skill of a worker in the art to select a known material (or, in this case, drug or bioactive agent) on the basis for its suitability for the intended purpose (in this case, to provide therapeutic treatment) as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant disclosed by Lynch with the therapeutic agents disclosed by Nelson in order to provide the desired therapeutic treatment to the patient.

8. Claims 1, 2, 4, 5, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,554,918 to White in view of US 2005/0119737 to Bene et al.

In the specification and figures, White discloses an ocular implant that is configured with one end in the anterior chamber of the eye and another end in a physiological outflow pathway such as a vortex vein to provide drainage therethrough. White fails to disclose the delivery of a therapeutic drug. However, Bene discloses an ocular implant with a body 106 that may comprise a drug or bioactive agent impregnated within or as a coating on the housing in order to provide drug delivery to the eye (see FIG 2, paragraphs 0033, 0046, 0059). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a drug coating as disclosed by Bene to the implant disclosed by White in order to provide drug delivery to the eye, as taught by Bene.

Response to Arguments

9. Applicant's amendment and arguments filed 28 June 2007 have been entered and considered.

10. Applicant's arguments with respect to the pending claims are unpersuasive.

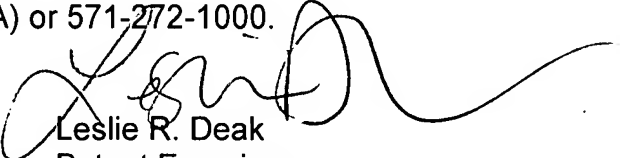
11. Applicant argues that the Lynch provisional application, dated 26 April 1999, fails to disclose an implant comprising a body of biocompatible material that may comprise a drug deliverable to surrounding tissues. However, the Examiner respectfully disagrees. On pages 11 and 13-14 of Lynch's provisional application, Lynch discloses the device as claimed by applicant and further discloses an implantable device that delivers drug to adjacent tissues. Accordingly, the provisional application provides sufficient enablement under 25 USC 112, 1st paragraph for the disclosed apparatus and method in US 6,450,984 to Lynch, and qualifies as prior art as per MPEP 2136.03 (III). Since the Lynch disclosure antedates applicant's earliest priority date, it qualifies as prior art under 35 USC 102(e), and the instantly claimed apparatus and method is unpatentable over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
16 August 2007